



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MEMORANDUM

OFFICE OF THE
SCIENCE ADVISOR

SUBJECT: Request for Directives Clearance Review of Revision to Order 1000.17 A1:
Policy and Procedures on Protection of Human Research Subjects in EPA
Conducted or Supported Research

FROM: Thomas A. Burke, PhD, MPH
EPA Science Advisor

TO: Cheri M. Hembrey, Director
Program Management and Communications
Office of Human Resources

PURPOSE

Attached for the Directives Clearance Review Process is a revision to Order 1000.17 A1, *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research*. The current Order was approved May 27, 2011 and amended on July 27, 2011.

BACKGROUND

EPA Order 1000.17 A1, EPA's policy for the protection of human subjects in research conducted or supported by EPA, has not been substantively updated since 1999. The 2011 amendment to the Order simply consisted of adding language that reinforced that all human observational exposure studies would be conducted in accordance with the principles outlined in the agency document *Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES)*.

Since then, research practice and agency practice have evolved. The federal protection for human subjects involved in research is codified by EPA at 40 CFR 26. The goal of this endeavor is to ensure that the Policy Order – the agency's guide to implementing 40 CFR 26 – reflects both accurate regulatory language and contemporary research practice. The revisions that follow are all in service of this goal.

OUTLINE OF CHANGES

While there have been small changes to make language consistent with the community of practice, the major changes to the Order are summarized here, by section, for convenience.

Definitions

- Removed definitions that no longer appear in the regulation or that were misquoted
- Added regulatory and policy definitions that are cited in the Order or are EPA-specific
- Reorganized the definitions so that they follow the order specified in the regulation

Policy

- Streamlined the language to make it more direct
- Ensured that the policy reflected actual practice and regulatory requirements
- Removed requirement for grants, contracts, inter-agency agreements (IAAs), etc. to be conditionally approved by the Human Subjects Research Review Official (HSRRO) before funding. This practice leaves the agency vulnerable, confuses grantees, and is not required by the regulation.
- Added a note that preliminary review by the HSRRO of grants, contracts, IAAs, etc. is possible, but that approval can only be given once Institutional Review Board (IRB) approval is in place (per the regulation).
- Moved information about foreign research from a separate section of the order into the policy section because the information is in 40 CFR Part 26.

Requirements

- Updated text to reflect regulatory language
- Clarified requirements to reflect contemporary practice and to ensure that the Order remains regardless of upgrades to IRB processes
- Reorganized the requirements according to contemporary research practice

Responsibilities

- Streamlined the language to make it more direct; removed potentially misleading language
- Updated descriptions to reflect actual practices and clarify expectations
- Added section on local Human Subject Officers
- Added a section for Principal Investigators, since they have ultimate responsibility for the conduct of the research project

Foreign Studies

- Removed this section and instead inserted a statement about foreign studies into the Policy section

WORK GROUP PROCESS

Dr. Toby Schonfeld, Director of the Program in Human Research Ethics and Oversight and the Human Subjects Research Review Official (HSRRO), worked closely with Lauren Maher, Office of General Counsel, to revise EPA Order 1000.17 A1. Dr. Melinda Gormley, a Science and Technology Policy Fellow of the American Association for the Advancement of Science, collected policies from other federal departments and agencies to inform the revisions. Some language in the revisions has been modeled on the Department of Energy's Order 443.1B, *Protection of Human Research Subjects*.

The revision was then reviewed by the management in the Office of the Science Advisor, as well by both the Executive Committee and full membership of the Human Research Ethics Council (HREC), a cross-agency council formed to promote consensus on Agency policies and procedures for research involving human participants and to advise the HSRRO on matters of policy development, training, and implementation. The HREC concurred with the revisions being submitted here; a copy of this concurrence is being submitted along with this request.

Members of the HREC are available to their respective laboratories, centers, offices, or regions to answer questions about this process and the resulting product. A copy of the current roster of the HREC is also being submitted with this request.

TECHNICAL CONTACT

Should you or your staff have any questions about this request, please contact Dr. Toby Schonfeld, Human Subjects Research Review Official, at 202-564-2550 or schonfeld.toby@epa.gov. Her mail code is 8105R.

RECOMMENDATION

I recommend that this revision to Order 1000.17 A1 be placed into the Directives Clearance Process as soon as possible. Thank you in advance for your prompt attention to this request.